Risk Assessment
Bovine Tuberculosis in Australia

Introduction

This report evaluates the probability that Australia is free of bovine tuberculosis (Mycobacterium bovis) as defined in the Organization International des Epizooties (OIE) Animal Health Code, and as defined by USDA-APHIS for a bovine tuberculosis Accredited-Free State. The report is based on an evaluation of the eleven risk factors identified in the Policy Statement accompanying the APHIS_s Regionalization Final Rule. Information for the assessment was provided by the Government of Australia.

The eleven risk factors are:

Authority, organization, and infrastructure of veterinary services;
Disease surveillance;
Diagnostic laboratory capabilities;
Disease outbreak history and disease prevalence;
Active disease control programs, if any;
Vaccination status;
Disease prevalence and outbreak history in adjacent regions;
Separation of the region from regions of higher risk through physical or other barriers;
Control of movements of animals and animal products from regions of higher risk;
Livestock demographics and marketing practices; and
Animal health policies and infrastructure for animal disease control;

Definitions

The OIE and USDA-APHIS have technical definitions for bovine tuberculosis (BTb) freedom.

OIE Animal Health Code definition

Chapter 3.2.3, Article 3.2.3.1 states:

_To qualify as officially free from bovine tuberculosis, a country or part of the territory of a country shall satisfy the following requirement:

1) bovine tuberculosis is compulsorily notifiable in the country;

2) 99.8% of the herds in the considered geographical area have been officially free from bovine tuberculosis for at least the past three years as disclosed by periodic testing of all cattle in the area to determine the absence of bovine tuberculosis (periodic testing of all cattle is not required

in an area where a surveillance programme as described in paragraph 4) below, reveals that at

least 99.9% of the cattle have been in officially tuberculosis-free herds for at least six years);

3) cattle introduced into a country or part of the territory of a country officially free from bovine tuberculosis must be accompanied by a health certificate from an *Official Veterinarian* attesting their compliance with Article 3.2.3.9 or the criteria set out in this Article;

4) a country or part of the territory of a country officially free from bovine tuberculosis must have a *Veterinary Administration* which should be able to trace and test the herd of origin of any reactor to a tuberculin test disclosed after removal from the considered territory. Also animals which at a *post-mortem* examination carried out by a veterinarian in an *abattoir* or elsewhere disclosed gross pathological lesions of tuberculosis which where necessary can be confirmed by established methods of microscopical-biological or cultural examination. In addition, such a country or part of territory of a country officially free from bovine tuberculosis must have in place a surveillance programme to ensure the discovery of bovine tuberculosis should the disease be present in the country or part of the territory of a country, through slaughter monitoring and/or tuberculin testing._

Chapter 3.2.3, Article 3.2.3.9 states

_*Veterinary Administrations* of *importing countries* should require:

for fresh meat of cattle and pigs

the presentation of an *international sanitary certificate* attesting that the entire consignment of meat comes from animals which were subjected to *ante* and *post-mortem* veterinary inspection and were found to be free from bovine tuberculosis._

<u>USDA-APHIS Bovine Tuberculosis Accredited-Free State (CFR 9 Part 77)</u>

77.1 (1) (I) _To establish or maintain status as an accredited-free state, a state must have no findings of tuberculosis in any cattle or bison in the state for at least 5 years. The state must also comply with all of the provisions of the _Uniform Methods and Rules--Bovine Tuberculosis Eradication_ regarding accredited-free states and must apply these provisions to bison in the same manner as to cattle. Detection of tuberculosis in any cattle or bison in the state will result in suspension of accredited-free state status. Detection of tuberculosis in cattle or bison in two or more herds in the state within 48 months will result in revocation of accredited-free status. Accredited-free state status must be renewed annually._

77.1 (2) (1) (ii) _A State is qualified for redesignation of accredited-free status after the herd in which tuberculosis is detected has been quarantined, an epidemiological investigation has confirmed that the disease has not spread from the herd, and all reactor cattle and bison have been destroyed. If any livestock other than cattle or bison are included in a newly assembled herd on a premises where a tuberculous herd has been depopulated, the State must apply the herd test

requirements of the _Uniform Methods and Rules--Bovine Tuberculosis Eradication_ for such newly assembled herds to those other livestock in the same manner as to cattle and bison._

Dr. Joseph Van Tiem (9) noted that the United States and Australia have had substantially different strategies for eradicating BTb. The United States strategy emphasized repeated testing of BTB affected herds with slaughter of reactor animals. This reduced short-term program expense but prolonged the time required to achieve complete eradication. Australia, on the other hand, has emphasized immediate depopulation of BTb affected herds. This reduced the probability of spread from infected herds and likely shortened the time required for complete eradication. It may have increased short-term program expenses however.

Because Australia and the United States have used different BTb eradication strategies, direct comparison of eradication requirements and program stages between the two countries is not appropriate for evaluating disease risk. A more useful approach is to apply the principle of equivalence as defined in the WTO-SPS Agreement, Article 4, Section 1. Article 4, Section 1 states:

_Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member_s appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing, and other relevant procedures._

Risk Factors for *M. bovis* in Australia

Authority, organization, and infrastructure of veterinary services

Australian States and Territories are responsible for disease control and eradication within their own boundaries. The commonwealth provides advice and coordination, and in some circumstances, financial assistance for national disease eradication programs. Each State/Territory is subdivided into veterinary regions or divisions under the control of a government veterinary officer. Each region or division is further subdivided into either animal health districts or rural lands protection boards which are administered by inspectors who may be veterinarians or qualified animal health technicians.

To support BTb eradication, Australia developed the Tuberculosis Freedom Assurance Program (TFAP) (2). This is a cooperative agreement between the Commonwealth of Australia, the States and Territories, and animal health industry and oversight groups providing a framework for BTb programs. TFAP outlines specific responsibilities, funding, level and timing of disease surveillance and/or emergency response activities, as well as standards for sample collection and testing protocols. Appropriate regulations authorize government veterinary officers to test, quarantine, slaughter, and pay indemnities for animals identified through TFAP or other disease

program efforts.

Australia has approximately 540 professionally qualified veterinarians employed by Commonwealth and State/Territorial governments (8% of the 6700 veterinarians in the country). Government veterinarians are supported by 4400 animal health technicians. An additional 5230 veterinarians (78%) are in private practice and are required to report any suspected cases of BTb.

Evaluation: APHIS believes Australia has sufficient legal authority, organization, and veterinary infrastructure to detect, control and eradicate BTb.

Disease surveillance in the region

TFAP includes provisions for the National Granuloma Submission Program (NGSP), a surveillance system to detect BTB in cattle sent to slaughter (2). NGSP outlines objectives, responsibilities, and methods for submitting tissue samples from abattoirs. All granulomas are examined by both histopathology and culture techniques. One objective of the program is to submit at least one sample per 2000 head of cattle slaughtered. Additional BTb surveillance is conducted on animals selected for export. Finally, BTb is a reportable disease throughout Australia and any suspicion of BTb results in an epidemiological investigation. Reports of cases or suspected cases, as well as all contact herds or herds identified during traceback, are tested for BTb with the bovine gamma interferon test.

Evaluation: APHIS believes that surveillance for BTb in Australia is adequate. APHIS notes that the Australian BTb surveillance program is essentially identical to BTb surveillance in the United States under the Uniform Methods and Rules (UMR).

Diagnostic laboratory capabilities.

State Veterinary Laboratories offer histopathology, culture and isolation services for BTb. Each State or Territory in Australia has at least one veterinary diagnostic lab approved for isolation of *M. bovis*. In addition to these State/Territory labs, the Western Australian Tuberculosis Laboratory was designated as the Australian Reference Laboratory for Bovine Tuberculosis (ARLBTB) in 1992 and as an OIE International Reference Lab in June, 1993. All isolates identified in approved State/Territory labs must be submitted to the ARLBTB for confirmation and long-term storage in the National Culture Collection, and for DNA fingerprinting (2).

Procedures for the preventing zoonotic diseases are in place in all labs. Provision of adequate occupational health and safety procedures for laboratory personnel prevent reintroduction of the pathogen into cattle. State/Territory labs require either minimum qualifications, a tertiary diploma, or bachelors degree for scientific supervisory personnel. All diagnostic work is under scientific supervision. The ARLBTB is responsible for the continuing education of laboratory staff.

The Australian National Quality Assurance Program (ANQAP) conducts annual quality assurance testing for veterinary diagnostic procedures in Australia and New Zealand. ANQAP evaluated the performance of seven labs during 1997. All labs correctly identified negative samples, and samples with *M. bovis* containing 22,000 colony forming units (CFU) and 220 cfu. When samples with as few as 22 cfu were tested, one laboratory correctly identified the sample positive for *M. bovis* on two trials. Four other laboratories identified one of two samples with *M. bovis* at 22 cfu during duplicate testing (8). The ANQAP determined that performance at all laboratories was acceptable.

Evaluation: APHIS finds that Australia has adequate diagnostic capability for BTb.

Disease outbreak history and disease prevalence

The Agriculture and Resource Management Council of Australia and New Zealand declared Australia a Free Area on 31 December, 1997 when:

a) all areas of Australia were Free or Impending Free for at least 5 years (_Impending Free_ is defined as an area with 1) an approved monitoring system in place, 2) all herds within the area assessed, 3) no herd Infected or Restricted [previously infected herd with one negative herd test at least 60 days after the last positive test], and 4) capacity to eradicate any BTb found within 24 months of detection. _Free_ is defined as an area that 1) had been Impending Free for at least 5 years during which the number of cases of BTb was acceptable and all BTb is believed to have been eradicated, 2) has all previously infected herds under surveillance, and 3) has an approved abattoir and granuloma submission system.);

b) the Veterinary Committee was satisfied that all BTb had been eradicated;

c) no herds were classified as Infected or Restricted (defined above), or Provisionally Clear [previously infected herd with two consecutive negative tests at an interval of not less than six months.];

d) movement controls were in place for cattle from herds that had BTb and achieved Confirmed Free One (CF1) Status [defined as a Provisionally Clear, Tested Negative or Monitored Negative herd that has had at least one further negative test without evidence of BTb at an interval of not less than six months after achieving that status.]; and

e) an approved abattoir surveillance system and granuloma submission program were in place (2).

As of the time of submitting information to APHIS, *M. bovis* has been identified once in 1998. This was in one of approximately 3,000,000 cattle inspected at slaughter. Traceback from that isolation resulted in slaughter of 2,500 contact cattle and 9,000 at-risk cattle.

Isolations of *M. bovis* from granuloma submissions at abattoirs are given below:

	Year		
	1995	1996	1997
# Isolations	7	10	5

Appropriate traceback of animals identified through the granuloma submission program at abattoirs, and epidemiological investigation of the herd or origin was accomplished. Slaughter and compensation were used during the years immediately preceding the declaration of BTb freedom to eliminate residual infection.

The OIE declared Australia free from BTb on DATE.

Evaluation: Australia has approximately 145,000 cattle herds (see *Demographics* below). OIE Animal Health Code Article 3.2.3.1 (2) requires that for a region to be declared free, 99.8% of herds must be BTb free for the previous three years. Even if every known isolation of BTb in the last three years represented a separate herd, Australia would satisfy the OIE requirement by a wide margin.

Active disease control programs, if any

Australia maintains active abattoir surveillance and granuloma submission as described above. If any cattle are identified as infected with *M. bovis*, the index case and all contact cattle are depopulated, and the owner is compensated through an indemnity program. Epidemiological investigation would be used to identify the source and possible spread of the disease.

Evaluation: Australia has an active BTb disease control program that is at least equivalent to and perhaps even more effective than the United States_ program. Australia has appropriate personnel for meat inspection, laboratory diagnosis, and epidemiological investigation, as well as the funding and authority for herd testing, depopulation, and compensation for slaughtered herds. (In contrast, the United States does not automatically require depopulation of BTb affected herds.) APHIS finds that Australia_s active disease control program is adequate.

Vaccination status of the region

Australia does not vaccinate for BTb.

Disease prevalence and outbreak history in adjacent regions.

Australia has no contiguous regions. The closest noncontiguous land mass to Australia is Papua New Guinea, which is separated from Australia by the 120 kilometer wide Torres Straits. No known movement of cattle occurs across the Torres Straits.

Evaluation: Adjacent regions pose no identifiable risk to Australia for BTb.

Separation of the region from regions of higher risk through physical or other barriers

Australia is an island nation, completely separated from all other regions by ocean on all sides. The closest land mass, Papua New Guinea, is 120 kilometers distant.

Evaluation: Oceans provide sufficient physical barriers to effectively isolate Australia from any areas of higher risk for BTb.

Control of movements of animals and animal products from regions of higher risk

Australia imports cattle from the United States, the European Union, New Zealand, Republic of South Africa, Canada, Switzerland, and Norway. Quarantine regulations require that imported cattle have been resident in a herd identified as officially free of BTb for at least 2 years immediately prior to export. A herd officially free of BTb is one with at least two negative herd tests within six months, the first being at least six months after the eradication of BTb from the herd. To maintain this officially free herd status, the herd of origin must be retested annually. In addition, the herd of origin must be in an area in which 99.8% of bovine herds have been officially free for the past three years and 99.9% of cattle have been in officially free herds for the past six years. Animals selected for export to Australia must test negative on the intradermal tuberculin caudal fold test within the 30 day period immediately prior to export, and have a repeat test within 90 following importation (5).

Evaluation: APHIS believes that Australia_s import requirements are sufficient to ensure that Australia is unlikely to be reinfected with BTb by imported live cattle. Australia complies with Article 3.2.3.1 (3) of the OIE Animal Health Code.

Livestock demographics and marketing practices in the region

Australia requires that every cattle herd in the country be identified with a tailtag. There are approximately 145,000 cattle herds in Australia. Some commercial enterprises may have more than one herd on a property. The Australian Bureau of Agriculture and Resource Economics (ABARE) had identified 44,600 enterprises with cattle whose agricultural operations are valued at over $22,500 (Australian dollars). The 1997 census for cattle in Australia is summarized in the table below:

Table 1: Cattle Numbers (x 1,000) by Type and State/Territory, 1997

	NSW	*Vic*	*Qld*	*SA*	*WA*	*Tas*	*NT*	*ACT*	*Aus*
Beef	*6038*	*2519*	*10071*	*1049*	*1859*	*536*	*1204*	*11*	*23287*
Dairy	*397*	*1849*	*302*	*164*	*128*	*226*	*1*	*0*	*3057*
Total	*6425*	*4368*	*10373*	*1213*	*1987*	*762*	*1205*	*11*	*26344*

The majority of cattle in Australia are beef cattle, with the largest populations in Queensland (40%) and New South Wales (24%), which together account for more than 2/3 of all the cattle in Australia. Major livestock markets are situated in major rural towns and adjacent to capital cities within each region. Cattle presented to slaughter markets or abattoirs are required to be identified to the herd of origin by certified tailtag registered with the veterinary authorities in each state.

Evaluation: APHIS believes that Australia has an adequate system for identifying cattle and cattle herds. APHIS further believes that Australia_s inventory of cattle herds is sufficient to permit determination of Australia_s compliance with OIE requirements for recognizing a country or region BTb free.

Animal health policies and infrastructure for animal disease control in the region

The TFAP provides guidelines for ongoing testing and surveillance. If an animal or carcass tests positive for *M. bovis* through serology, histopathology, or the intradermal tuberculin test, the index case and all contact animals are depopulated, and an epidemiological investigation is used to identify additional at-risk animals and/or herds. These additional at-risk animals are either depopulated or tested, depending on recommendation of animal health authorities. Throughout these procedures, herds in question are under quarantine. Restrictions on movement are in place until released by the State/Territory veterinary authority.

Evaluation: APHIS believes that Australia has adequate policies and animal health infrastructure for identifying and controlling outbreaks of BTb if any were to occur.

Risk Characterization

Based on the evidence presented above, APHIS finds that:

1. Australia has sufficient legal authority, organization, and veterinary infrastructure to respond adequately to outbreaks of BTb;
2. Australia has adequate surveillance to detect BTb if it were present;
3. Australia has adequate laboratory capability to diagnose BTb;
4. Australia has had reported outbreaks of BTb in 1995, 1996, 1997, and 1998. The herd prevalence in 1996, 1997, and 1998 was less than 0.01% in all three years. This satisfies the OIE requirement for recognition as a free country;
5. Australia is competent to implement an active BTb eradication and control program;
6. Australia has does not vaccinate cattle for BTb;
7. Australia has no adjacent, contiguous regions or countries in which BTb is known to exist;
8. Australia has physical or other barriers providing adequate separation from regions and countries where BTb is known to exist;

9. Australia has adequate import restrictions to control movement of animals and animal products from regions or countries in which BTb is known to exist;
10. Australia has an adequate system for identifying cattle and cattle herds; and
11. Australia has adequate policies and infrastructure for controlling and preventing BTb.

APHIS finds that Australia has a BTb control and eradication program in place that is equivalent in impact and disease risk to APHIS_s Uniform Methods and Rules. Although Australia does not meet APHIS_s technical definition for an Accredited-Free State, that definition assumed that states would achieve free status by repeated testing of affected herds with removal of reactor animals. Because this is a relatively slow method of eradicating the disease in an affected herd, because affected herds may spread BTb to other herds even though they are under quarantine, and because ante-mortem screening tests for BTb are relatively insensitive when applied to individual animals, the UMR requires a relatively long time period without known outbreaks for states to achieve accredited-free status.

Consistent with Article 4, Section 1 of the WTO-SPS Agreement, APHIS believes that countries or regions that immediately depopulate BTb affected herds may achieve a level of risk equivalent to that of Accredited-Free states, even if these countries or regions have had disease detected within the last five years. Australia is such a country. If Australia had previously been designated an Accredited-Free State, it would now meet the requirements for redesignation of accredited-free status. Indeed, by depopulating the only herd known to have had BTb in 1998, Australia exceeds the UMR requirement for redesignated status. Recognizing that for all of the eleven risk parameters discussed above, Australia is at least comparable or equivalent to an Accredited-Free State, APHIS concludes that the BTb risk due to animals and animal products imported from Australia is equivalent to that for the interstate movement of animals and animal products from an Accredited-Free State.

APHIS_s Uniform Methods and Rules for the interstate movement of bovines from an Accredited-Free State either for breeding, feeding, or slaughter do not require testing for BTb. The WTO-SPS Agreement Article 2, Section 3 requires that members ensure that _their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and other Members._ APHIS has determined that the BTb risk due to movement of animals from Accredited-Free States, when moved in compliance with the requirements of the UMR is acceptable. Similarly, and in compliance with the WTO-SPS Agreement, APHIS now finds that the BTb risk due to the importation of animals and animal products from Australia is acceptable, provided that such imports comply with a risk mitigation strategy comparable to that for the interstate movement of animals and animal products from an Accredited-Free State.

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